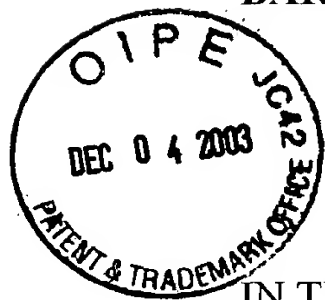


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group: 1743
Confirmation No.: 5090
Application No.: 09/541,552
Invention: BIOSENSOR
ELECTROMAGNETIC NOISE
CANCELLATION
Applicant: Maury Zivitz
Filed: April 3, 2000
Attorney: 5727-72828
Docket:
Examiner: Arlen Soderquist

Certificate Under 37 CFR 1.8(a)

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on December 1, 2003

Kim Tyree
(Signature)

Kim Tyree

(Printed Name)

LETTER

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The Commissioner for Patents
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Sir:

The following remarks are submitted in response to the August 29, 2003 official action.

The Examiner rejected claims 1-20 and 24-42 based upon the combination of Parks U. S. Patent 4,999,582 (hereinafter **Parks**) combined with H. W. van Rooijen and H. Poppe, "Noise And Drift Phenomena In Amperometric And Coulometric Detectors For HPLC And FIA," Journal Of Liquid Chromatography, 6 (12), 2231-2254 (1983) (hereinafter **van Rooijen**), further combined with any one of Shults, W. D., F. E. Haga, T. R. Mueller and H. C. Jones, "Chronopotentiometer With Compensation For Extraneous Currents," Analytical Chemistry, 37 (11), 1415-1416 (1965) (hereinafter **Shults**), Eifler U. S. Patent 4,233,033

(hereinafter **Eifler**), Yasuda U. S. Patent 4,244,918 (hereinafter **Yasuda ‘918**), Yasuda U. S. Patent 4,277,439 (hereinafter **Yasuda ‘439**), Yasuda U. S. Patent 4,303,613 (hereinafter **Yasuda ‘613**), Tien U. S. Patent 4,387,359 (hereinafter **Tien**), Raymond U. S. Patent 4,571,543 (herinafter **Raymond**), Wohltjen U. S. Patent 4,572,900 (hereinafter **Wohltjen**), Stanbro U. S. Patent 4,935,207 (herinafter **Stanbro**) or Pribat U. S. Patent 5,017,340 (hereinafter **Pribat**).

The Examiner relies upon **Parks** to teach an amperometric biosensor including two spaced apart electrodes 12, 14 which form a measurement loop that includes a test cell 10 on a substrate 16. The test cell includes a cover sheet 18 provided with openings 20, 24 through which the electrodes are exposed. A reaction zone is defined adjacent one, 20, of the openings. The reaction current is referred to as Cottrell current. The Examiner concedes that **Parks** does not teach a noise cancellation loop to cancel the effects of electromagnetically propagated energy.

Parks neither discloses nor suggests claim 1’s specifically recited “noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly.”

Parks neither discloses nor suggests claim 24’s specifically recited “method for adjusting the output of a Cottrell current-type biosensing cell assembly comprising . . . providing a noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly.”

The Examiner observes that **van Rooijen** discusses three different methods for ascertaining a relation between the capacitance of the working electrodes of such electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis and the noise generated in such detectors. The three methods noted by the Examiner are: (1) direct correlation of noise with capacitance; (2) time correlation functions; and, (3) electrical simulation of the properties of the cells of such electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis. The Examiner notes that **van Rooijen** specifically mentions at

page 2232 several different causes of drift and noise including temperature fluctuations and electronic equipment.

van Rooijen neither discloses nor suggests claim 1's specifically recited "noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly."

van Rooijen neither discloses nor suggests claim 24's specifically recited "method for adjusting the output of a Cottrell current-type biosensing cell assembly comprising . . . providing a noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly."

The Examiner relies upon **Shults** to teach a chronopotentiometer with compensation for extraneous currents. The Examiner believes **Shults** teaches a second measurement loop for compensating for, for example, the charging of the electric double layers at the electrode-solution interface, the electrolysis of minor and major components of the solution, and the electrolytic reduction or oxidation of the electrode(s) itself (themselves). The Examiner calls Applicant's attention particularly to uncompensated and compensated chronopotentiograms (Fig. 2 of **Shults**) which, the Examiner believes, support the Examiner's reliance upon **Shults**.

Shults neither discloses nor suggests claim 1's specifically recited "noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly."

Shults neither discloses nor suggests claim 24's specifically recited "method for adjusting the output of a Cottrell current-type biosensing cell assembly comprising . . . providing a noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically

connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly.”

The Examiner relies upon each of **Eifler, Yasuda ‘918, Yasuda ‘439, Yasuda ‘613, Tien, Raymond, Wohltjen, Stanbro or Pribat** to teach a primary measuring circuit in a support with two electrodes connected to an analyte detection zone for measuring an analyte and a reference measuring circuit also on the support which is electrically distinct from the analyte detection zone and physically arranged to experience the same environment as the primary measuring circuit. The reference measuring circuit is used to cancel effects such as temperature that are known to affect the measuring circuit.

Eifler discloses a method and sensing apparatus 10 for obtaining an electrical signal which is a function of the oxygen content of the exhaust gas of an internal combustion engine. Two resistors, 1, 3, are exposed to the exhaust gas of an internal combustion engine. Both resistors 1 and 3 have resistances which vary as a function of the temperature of the exhaust gas to which they are exposed. The resistance of one of the resistors, 1, also varies as a function of the oxygen content in the exhaust gas. Therefore, by applying a voltage to the resistors, an electrical signal can be obtained which is a function of the oxygen content of the exhaust gas, with the temperature effect of the exhaust gas on the network output being compensated. The resistors, 1, 3, are connected in series to other resistors to form first and second resistor networks which are connected together in parallel circuit relationship.

Yasuda ‘918 discloses an internal combustion engine exhaust gas component detection apparatus comprising first and a second gas sensing elements, each composed of a metal oxide which exhibits variable electric resistances according to gaseous components and temperatures of gases to be detected. A catalyst is carried at least by the first sensing element for promoting oxidation reactions of the gaseous components of the gases. A first pair of electrodes are inserted into those portions of the first sensing element which are subjected to catalytic action of the catalyst. A second pair of electrodes are inserted into the portions of the second sensing element which are not subjected to catalytic action. The first pair of electrodes sense a variation in electric resistances resulting from the gaseous components and temperatures of the gases, while the second pair of electrodes detect an electric resistance variation related mainly to the gas temperatures. Consequently, an output signal reflecting substantially only the concentrations of the various components of the gases is produced by offsetting the separately sensed electric resistances utilizing a suitable electric circuit.

Yasuda ‘439 discloses an internal combustion engine exhaust gas component detector including a first gas component detecting element formed by a metal oxide having an

electric resistance depending on the concentration of gas components and on the temperature of a detected gas; and a second gas component detecting element formed by a metal oxide having the same temperature coefficient of electric resistance as that of the first gas component detecting element and an electric resistance depending on the concentration of gas components and on the temperature of the detected gas and a slower detection response time to the concentration of gas components in the detected gas than the response time of the first gas component detecting element.

Yasuda '613 discloses an internal combustion engine exhaust gas component detector including two sintered elements fixed to the tip of a tubular ceramic body. Both of the sintered elements are made of metal oxide which exhibits an electrical resistance change in response to changes in the engine exhaust gas component and the temperature of the exhaust gas. One of the sintered elements carries a catalyst to promote an oxidation reaction of the engine exhaust gas component. The other sintered element which does not carry a catalyst is connected in series with the one sintered element and provides temperature compensation of the electrical resistance change of the one sintered element. A fixed resistor having a resistance value considerably smaller than that of the other sintered element is connected in parallel with the other sintered element to maintain the apparent resistance of the other sintered element at a small value at low exhaust gas temperature.

Tien discloses an internal combustion engine exhaust gas component detector including a chrome oxide compensating resistor 5 in series with a titania sensing resistor 3. The chrome oxide resistor 5 compensates for the effects of temperature on the titania sensing resistor 3. Additionally, since the chrome oxide resistor 5 exhibits P type behavior and the titania sensing resistor 3 exhibits N type behavior in the presence of gaseous oxygen, the sensitivity of the sensor is increased. The resistors 3, 5 can be applied as a film to a substrate 7, or the resistors 3, 5 can be formed as discrete chips. Substantial quantities of alumina and glass can be added to the chrome oxide without affecting oxygen sensitivity although the electrical resistance rises substantially.

Raymond discloses electrically conductive strips of metal placed upon an insulative substrate to form two capacitor plates, the plates having a configuration of interdigitated fingers, concentric circles, intertwined spirals, or the like. Electrical leads for connection to ancilliary equipment attach in turn to each plate. Next, an electrically insulative coating of an appropriate material covers the electrically conductive capacitor plates and leads, this insulative covering being chosen to be completely passive, non-reactive, and non-absorptive to the specific material sought to be detected and to other chemicals and

materials present in the surrounding environment.

Wohltjen discloses a method and apparatus to automatically compensate for temperature variation in a vapor detection system. Two identical organic semiconductor film sensors in close thermal contact with each other are used in the feedback circuit of an inverting amplifier supplied by constant voltage. One of the sensors is isolated from vapor exposure to act as a reference for the other sensor which is used for vapor sampling. The output of the inverting amplifier provides an indication of the presence and relative concentration of vapor exposure. Variation in sample sensor resistance due to a change in temperature is accompanied by the same corresponding change in the reference sensor, which stabilizes the ratio of the feedback circuit resistances and therefore the gain of the inverting amplifier to exactly compensate for the temperature induced resistance variations automatically.

Following the insulative passive covering of the electrical strips and leads is a second layer of a selected membrane or the like. This second layer membrane may be a coating immediately covering the first insulative passive layer or it may be spaced apart from the insulative passive layer, in which case, there may be an intermediate medium, substantially non-reactive, such as a gas or liquid, interposed between the first insulative layer covering and the second layer membrane. The second layer membrane has a known relationship with the specific material to be detected, whether it be selectively absorptive, selectively porous, or possess some other selective physical property.

The specific material to be detected enters or passes the second layer to the immediate proximity of the first layer and thereby shows its presence by affecting the dielectric constant of the material within the electric field between the plates of the interdigitated capacitor.

The device is then connected into an external electrical circuit which enables the resulting change in capacitance of the interdigitated capacitor to be detected and measured. In the preferred embodiment, the subject interdigitated capacitor detection device is placed into a diode-quad capacitance measuring electrical circuit, which circuit impresses a voltage of known frequency and magnitude across the plates of the interdigitated capacitive detection device, and of a similarly constructed, proximate interdigitated capacitive device which, however, has been completely passivated by a totally non-reactive second layer or does not react with the environment. This permits the second, or passivated interdigitated capacitor to sense temperature of the environment. The change in capacitance between the two interdigitated capacitors is detected while both are situated in the same environment.

The magnitude of a D. C. voltage output of the electrical circuit is indicative of the differential change in the capacitance between the two interdigitated capacitors. Such differential change in capacitance and rate of change of capacitance is reflective of the amount of the specific material which has entered into, become collected, or passed the second membrane layer to enter into the electric field between the capacitor plates, change the constant of the dielectric of the interdigitated capacitor, and thus the capacitor's capacitance.

Stanbro discloses a capacitive chemical sensor that uses an ion exchange layer to detect analyte ions in a liquid medium. An ion exchange occurs on the surface of the ion exchange layer, wherein a portion of the counter-ions are removed from the surface in favor of analyte ions. The resulting movement of counter-ions from the surface of the ion exchange layer alters the dielectric constant of the liquid medium along the surface of the ion exchange layer. This change in dielectric constant produces a change in capacitance of the capacitive chemical sensor. **Stanbro** discloses a differential sensor embodiment comprising the ion exchange capacitive sensor, as described above, with a reference capacitive sensor. The accuracy is increased if differential sensing is employed. The reference capacitor compensates for changes in the dielectric constant of the liquid medium caused by changes in temperature, general ionic concentration and the physical and chemical state of the liquid medium.

Pribat discloses an oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers. A sensitive element, the resistivity of which is sensitive to an excess of one of the reactive species; a thermistor mounted as a resistance bridge with the sensitive element; and, a heating resistor fixing the minimum temperature threshold of operation, are disposed on a common substrate.

None of **Eifler**, **Yasuda '918**, **Yasuda '439**, **Yasuda '613**, **Tien**, **Raymond**, **Wohltjen**, **Stanbro** or **Pribat** either discloses nor suggests claim 1's specifically recited "noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly."

None of **Eifler**, **Yasuda '918**, **Yasuda '439**, **Yasuda '613**, **Tien**, **Raymond**, **Wohltjen**, **Stanbro** or **Pribat** either discloses nor suggests claim 24's specifically recited

“method for adjusting the output of a Cottrell current-type biosensing cell assembly comprising . . . providing a noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly.”

Other than in Applicant's disclosure, there is no disclosure or suggestion anywhere in the art of record of the desirability of combining the Cottrell current sensing instrument and slide of **Parks** with the methods for ascertaining a relation between the capacitance of the working electrodes of such electrochemical detectors and the noise generated in such detectors disclosed in **van Rooijen**. Further, even assuming that such a combination of **Parks** and **van Rooijen** would have been 35 U. S. C. § 103 obvious (a position Applicant vigorously disputes), other than in Applicant's disclosure there is no disclosure or suggestion anywhere in the art of record of the desirability of then further combining the **Parks/van Rooijen** combination with: the measurement loop for compensating for, for example, the charging of the electric double layers at the electrode-solution interface of **Shults**; or **Eifler's** method and sensing apparatus for obtaining an electrical signal which is a function of the oxygen content of the exhaust gas of an internal combustion engine; or the internal combustion engine exhaust gas component detection apparatus of **Yasuda '918**, **Yasuda '439**, or **Yasuda '613**; or **Tien's** internal combustion engine exhaust gas component detector; or the insulatively coated electrically conductive capacitor plates and leads, the insulative coating being chosen to be completely passive, non-reactive, and non-absorptive to the specific material sought to be detected and to other chemicals and materials present in the surrounding environment of **Raymond**; or **Wohltjen's** method and apparatus to automatically compensate for temperature variation in a vapor detection system including two identical organic semiconductor film sensors, one isolated from vapor exposure by being completely passivated by a totally non-reactive layer in order to act as a reference for the other sensor which is used for vapor sampling; or the ion exchange capacitive sensor and reference capacitive sensor with differential sensing of **Stanbro**; or **Pribat's** oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers.

There is no disclosure or suggestion in any 35 U. S. C. § 103 obvious combination of **Parks** and **van Rooijen** and any one of **Shults**, **Eifler**, **Yasuda '918**, **Yasuda '439**, **Yasuda '613**, **Tien**, **Raymond**, **Wohltjen**, **Stanbro** or **Pribat** of a “noise cancellation

loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly,” as required in each of Applicant’s claims. It is elemental that the prior art relied upon, either individually or in combination, must disclose or suggest all the limitations recited in the claims. See, e.g., In re Rijckaert, 9 F.3d 1531, 1533, 28 USPQ2d 1955, (Fed. Cir. 1993). Without establishing some disclosure or suggestion of the limitations of Applicant’s claims, the Examiner has not made out a *prima facie* case of obviousness. Id.

“The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.” In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125 (Fed. Cir. 1984). The Federal Circuit Court of Appeals has stated that a “bald assertion that ‘substitution of one type of detector for another in the [prior art] would have been within the skill of the art’” is insufficient for a finding of obviousness. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596 (Fed. Cir. 1988); see also Ex parte Levengood, 28 USPQ2d 1300, 1301 (Bd. Pat. App. & Inter. 1993) (“an assertion that one of ordinary skill in the relevant art would have been able to arrive at appellant’s invention because he had the necessary skills to carry out the requisite process steps” is “an inappropriate standard for obviousness”). Thus, there is no support in **Parks, van Rooijen, Shults, Eifler, Yasuda ‘918, Yasuda ‘439, Yasuda ‘613, Tien, Raymond, Wohltjen, Stanbro or Pribat** for the 35 U. S. C. § 103 obviousness of a combination including a “noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly.”

Further, “[w]hen obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.” B.F. Goodrich Co. v. Aircraft Braking Systems Corp., 72 F.3d 1577, 1582, 37 USPQ2d 1314 (Fed. Cir. 1996) (citations omitted). The Examiner has pointed to nothing in the prior art which suggests the desirability of modifying any of **Parks, van Rooijen, Shults, Eifler, Yasuda ‘918, Yasuda ‘439, Yasuda ‘613, Tien, Raymond, Wohltjen, Stanbro or Pribat** as necessary to achieve Applicant’s claimed arrangement.

Furthermore, any use of **van Rooijen, Shults, Eifler, Yasuda ‘918, Yasuda**

‘439, Yasuda ‘613, Tien, Raymond, Wohltjen, Stanbro or Pribat as a reference under 35 U.S.C. § 103 would be improper because they are not analogous to Applicant’s invention. In re Wood stated the rule for determining whether a prior art reference is or is not analogous art under 35 U.S.C. § 103:

In resolving the question of obviousness under 35 U.S.C. § 103, we presume full knowledge by the inventor of all the prior art in the field of his endeavor. However with regard to prior art outside the field of his endeavor, we only presume knowledge from those arts *reasonably pertinent* to the particular problem with which the inventor was involved.

599 F.2d 1032, 1036, 202 USPQ 171 (CCPA 1979) (emphasis added).

Accord, In re Clay, 966 F.2d 656, 659, 23 USPQ2d 1058 (Fed. Cir. 1992).

In recent cases, the Federal Circuit Court of Appeals has rejected prior art as non-analogous in situations where the prior art was at least as closely related to the claimed invention as in the present case. The Federal Circuit Court of Appeals has emphasized the practical, common sense aspects of the circumstances facing the inventor.

Patent examination is necessarily conducted by hindsight, with complete knowledge of the applicant’s invention, and the courts have recognized the subjective aspects of determining whether an inventor would reasonably be motivated to go to the field in which the examiner found the reference, in order to solve the problem confronting the inventor. We have reminded ourselves and the PTO that it is necessary to consider “the reality of the circumstances”--in other words, common sense--in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor.

In re Oetiker, 977 F.2d 1443, 1447, 24 USPQ2d 1443 (Fed. Cir. 1992) (citing In re Wood). As recent precedent illustrates, the Federal Circuit’s common sense approach precludes broad interpretations of an invention’s “field of endeavor” or what art is “reasonably pertinent.” **van Rooijen, Shults, Eifler, Yasuda ‘918, Yasuda ‘439, Yasuda ‘613, Tien, Raymond, Wohltjen, Stanbro and Pribat** relate to problems unrelated to Applicant’s invention for “cancellation . . . [of the] effect[s] of electromagnetically propagated field energy irradiating biosensor cell assembl[ies].”

Federal Circuit precedent requires that the analogous art inquiry focus on the field of endeavor for an invention. In Clay, the issue was whether a reference (Sydansk) which disclosed a process using a gel for reducing the permeability of hydrocarbon-bearing formations (useful in the recovery of oil from an oil field, for example) was analogous art to Clay’s claimed process for using a similar gel to fill a dead volume in the bottom of a liquid

hydrocarbon storage tank. Clay, 966 F.2d at 658.

The Federal Circuit observed that:

Sydansk cannot be considered to be within Clay's field of endeavor merely because both relate to the petroleum industry. Sydansk teaches the use of a gel in unconfined and irregular volumes within generally underground natural oil-bearing formations to channel flow in a desired direction; Clay teaches the introduction of gel to the confined dead volume of a man-made storage tank. The Sydansk process operates in extreme conditions, with petroleum formation temperatures as high as 115°C and at significant well bore pressures; Clay's process apparently operates at ambient temperature and atmospheric pressure. Clay's field of endeavor is the *storage* of refined liquid hydrocarbons. The field of endeavor of Sydansk's invention, on the other hand, is the *extraction* of crude petroleum. The Board clearly erred in considering Sydansk to be within the same field of endeavor as Clay's.

Id. at 659 (emphasis in original). Although both the invention and prior art related to using a gel in the petroleum industry, the Federal Circuit emphasized that the different applications and different physical environments in which the invention and prior art operated served to make the prior art non-analogous.

Applicant's claimed invention relates to methods and apparatus for a "noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly." **van Rooijen, Shults, Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro and Pribat** relate to problems unrelated to a "noise cancellation [in a test cell of a measurement loop on a substrate]." As a practical matter, an inventor in the field of methods and apparatus for addressing electromagnetically propagated field energy irradiating biosensor cell assemblies would not look to: **van Rooijen's** methods for ascertaining a relation between the capacitance of the working electrodes of electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis and the noise generated in such detectors; or **Shults's** charging of the electric double layers at the electrode-solution interface; or **Eifler's** method and sensing apparatus for obtaining an electrical signal which is a function of the oxygen content of the exhaust gas of an internal combustion engine; or **Yasuda '918's, Yasuda '439's, or Yasuda '613's** internal combustion engine exhaust gas component

detection apparatus; or **Tien's** internal combustion engine exhaust gas component detector; **Raymond's** insulatively coated electrically conductive capacitor plates and leads, the insulative coating being chosen to be completely passive, non-reactive, and non-absorptive to the specific material sought to be detected and to other chemicals and materials present in the surrounding environment; or **Wohltjen's** method and apparatus to automatically compensate for temperature variation in a vapor detection system including two identical organic semiconductor film sensors, one isolated from vapor exposure by being completely passivated by a totally non-reactive layer in order to act as a reference for the other sensor which is used for vapor sampling; or **Stanbro's** ion exchange capacitive sensor and reference capacitive sensor with differential sensing; or **Pribat's** oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers for guidance. Thus, under Federal Circuit precedent, **van Rooijen, Shults, Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro** and **Pribat** are not within the same field of endeavor as Applicant's claimed invention. Clay, 966 F.2d at 660; see, also, Wang Labs., Inc. v. Toshiba Corp., 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).

Federal Circuit precedent similarly refuses to require an applicant to scour the prior art for inventions that operate on similar principles as the applicant's invention. As the Federal Circuit highlighted in Oetiker, common sense limits the fields to which a person of ordinary skill would reasonably be expected to look for a solution.

Oetiker's invention was an improvement to a hose clamp, the clamp being the subject of a prior patent to Oetiker. The improvement added another feature, a preassembly hook, to the prior patent's clamp. The reference that the examiner combined with the prior patent teaching to support the 35 U.S.C. § 103 rejection related to a plastic hook and eye fastener for garments. The Federal Circuit Court of Appeals noted that:

The examiner explained [] that "Appellant's device as disclosed could be utilized as part of a garment." The Board did not repeat or support the examiner's argument, or discuss its relevance. Indeed, the argument is not supportable. However, the Board held that the Lauro reference, although not "within the appellant's specific field of endeavor" is nonetheless "analogous art" because it relates to a hooking problem, as does Oetiker's invention.

The Board apparently reasoned that all hooking problems are analogous.

Oetiker, 977 F.2d at 1446. The Federal Circuit then observed that:

Patent examination is necessarily conducted by hindsight, with complete knowledge of the applicant's invention, and the courts have recognized the subjective aspects of determining whether an inventor would reasonably be motivated to go to the field in which the examiner found the reference, in order to solve the problem confronting the inventor. We have reminded ourselves and the PTO that it is necessary to consider "the reality of the circumstances", *In re Wood*, 599 F.2d 1032, 1036, 202 USPQ 171, 174 (CCPA 1979)--in other words, common sense--in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor.

It has not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments. The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness.

Id. at 1447.

Just as the Federal Circuit in Oetiker criticized the Board's "[apparent reasoning] that all hooking problems are analogous," in the present case there is no basis for reasoning that all error correction problems are analogous. The problems related to "cancellation . . . [of the] effect[s] of electromagnetically propagated field energy irradiating biosensor cell assembly" are not reasonably pertinent to **van Rooijen's** methods for ascertaining a relation between the capacitance of the working electrodes of electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis and the noise generated in such detectors; **Shults's** charging of the electric double layers at the electrode-solution interface; **Eifler's** method and sensing apparatus for obtaining an electrical signal which is a function of the oxygen content of the exhaust gas of an internal combustion engine; **Yasuda '918's**, **Yasuda '439's**, and **Yasuda '613's** internal combustion engine exhaust gas component detection apparatus; **Tien's** internal combustion engine exhaust gas component detectors; **Raymond's** insulatively coated electrically conductive capacitor plates and leads; **Wohltjen's** methods and apparatus to automatically compensate for temperature variation in a vapor detection system; **Stanbro's** ion exchange capacitive sensor and reference capacitive sensor with differential sensing; or **Pribat's** oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers. Whereas **van Rooijen** addresses methods for ascertaining a relation between the capacitance of the working

electrodes of electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis and the noise generated in such detectors; **Shults** addresses charging of the electric double layers at the electrode-solution interface; **Eifler** addresses method and sensing apparatus for obtaining an electrical signal which is a function of the oxygen content of the exhaust gas of an internal combustion engine; or **Yasuda ‘918**, **Yasuda ‘439**, and **Yasuda ‘613** address internal combustion engine exhaust gas component detection apparatus; **Tien** addresses internal combustion engine exhaust gas component detectors; **Raymond** addresses insulatively coated electrically conductive capacitor plates and leads, the insulative coating being chosen to be completely passive, non-reactive, and non-absorptive to the specific material sought to be detected and to other chemicals and materials present in the surrounding environment; **Wohltjen** addresses methods and apparatus to automatically compensate for temperature variation in a vapor detection system including two identical organic semiconductor film sensors, one isolated from vapor exposure by being completely passivated by a totally non-reactive layer in order to act as a reference for the other sensor which is used for vapor sampling; **Stanbro** addresses ion exchange capacitive sensor and reference capacitive sensor with differential sensing; **Pribat** addresses oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers, Applicant’s invention addresses the “cancellation . . . [of the] effect[s] of electromagnetically propagated field energy irradiating biosensor cell assembl[ies].” Under the Federal Circuit’s “reality of the circumstances” or “common sense” rationale, it is unrealistic and not common sense to expect an inventor in the art of biosensor cell assemblies to look to: the electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis of **van Rooijen**; the charging of electric double layers at electrode-solution interfaces of **Shults**; the methods and sensing apparatus for obtaining an electrical signal which is a function of the oxygen content of exhaust gas of an internal combustion engine of **Eifler**; the internal combustion engine exhaust gas component detection apparatus of **Yasuda ‘918**, **Yasuda ‘439**, and **Yasuda ‘613**; the internal combustion engine exhaust gas component detectors of **Tien**; the insulatively coated electrically conductive capacitor plates and leads of **Raymond**; the methods and apparatus to automatically compensate for temperature variation in a vapor detection system of **Wohltjen**; the ion exchange capacitive sensors and reference capacitive sensors with differential sensing of **Stanbro**; or, the oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers of **Pribat**.

The Examiner further rejected claims 1-20 and 24-42 based upon the combination of White U. S. Patent 5,352,351 (hereinafter **White**) combined with **van Rooijen**, further combined with any one of **Shults, Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro or Pribat**.

The Examiner relies upon **White** to teach a biosensing meter and a sample strip 10 having two spaced apart, electrically isolated electrodes 12, 14, forming a measurement loop that includes a reaction zone on a substrate 16. The sample strip includes a cover sheet 18 provided with openings 20, 21, which expose the electrodes. One opening, 20, forms a well and defines a reaction zone between the electrodes. The second opening, 21, exposes the electrodes so that when sample strip 10 is inserted into the biosensing meter, electrical connection can be made thereto. The Examiner concedes that **White** does not teach a noise cancellation loop to cancel the effects of electromagnetically propagated energy. The Examiner relied upon **van Rooijen, Shults, Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro and Pribat** as previously noted.

White neither discloses nor suggests claim 1's specifically recited "noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly."

White neither discloses nor suggests claim 24's specifically recited "method for adjusting the output of a Cottrell current-type biosensing cell assembly comprising . . . providing a noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly."

And, as previously noted, none of **van Rooijen, Shults, Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro or Pribat** either discloses nor suggests claim 1's specifically recited "noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly."

Also as previously noted, none of **van Rooijen**, **Shults**, **Eifler**, **Yasuda '918**, **Yasuda '439**, **Yasuda '613**, **Tien**, **Raymond**, **Wohltjen**, **Stanbro** or **Pribat** either discloses nor suggests claim 24's specifically recited "method for adjusting the output of a Cottrell current-type biosensing cell assembly comprising . . . providing a noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly."

Again, other than Applicant's disclosure, there is no disclosure or suggestion anywhere in the art of record of the desirability of combining the Cottrell current sensing instrument and slide of **White** with the methods for ascertaining a relation between the capacitance of the working electrodes of such electrochemical detectors and the noise generated in such detectors disclosed in **van Rooijen**. Further, even assuming that such a combination of **White** and **van Rooijen** would have been 35 U. S. C. § 103 obvious (a position Applicant vigorously disputes), other than Applicant's disclosure, there is no disclosure or suggestion anywhere in the art of record of the desirability of then further combining the **White/van Rooijen** combination with: **Shults's** measurement loop for compensating for, for example, the charging of the electric double layers at the electrode-solution interface; or the method and sensing apparatus for obtaining an electrical signal which is a function of the oxygen content of the exhaust gas of an internal combustion engine of **Eifler**; or the internal combustion engine exhaust gas component detection apparatus of **Yasuda '918**, **Yasuda '439**, or **Yasuda '613**; or the internal combustion engine exhaust gas component detector of **Tien**; or **Raymond's** insulatively coated electrically conductive capacitor plates and leads, the insulative coating being chosen to be completely passive, non-reactive, and non-absorptive to the specific material sought to be detected and to other chemicals and materials present in the surrounding environment; or the method and apparatus to automatically compensate for temperature variation in a vapor detection system including two identical organic semiconductor film sensors, one isolated from vapor exposure by being completely passivated by a totally non-reactive layer in order to act as a reference for the other sensor which is used for vapor sampling of **Wohltjen**; or **Stanbro's** ion exchange capacitive sensor and reference capacitive sensor with differential sensing; or **Pribat's** oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers.

There is no disclosure or suggestion in any 35 U. S. C. § 103 obvious

combination of **White** and **van Rooijen** and any one of **Shults, Eifler, Yasuda ‘918, Yasuda ‘439, Yasuda ‘613, Tien, Raymond, Wohltjen, Stanbro** or **Pribat** of a “noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly,” as required in each of Applicant’s claims. Again, the prior art relied upon, either individually or in combination, must disclose or suggest all the limitations recited in the claims. Without establishing some disclosure or suggestion of the limitations of Applicant’s claims, the Examiner has not made out a *prima facie* case of obviousness. In re Rijckaert, supra.

“The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.” In re Gordon, supra. The Federal Circuit Court of Appeals has stated that a “bald assertion that ‘substitution of one type of detector for another in the [prior art] would have been within the skill of the art’” is insufficient for a finding of obviousness. In re Fine, supra; Ex parte Levengood, supra. Thus, there is no support in **White, van Rooijen, Shults, Eifler, Yasuda ‘918, Yasuda ‘439, Yasuda ‘613, Tien, Raymond, Wohltjen, Stanbro** or **Pribat** for the 35 U. S. C. § 103 obviousness of a combination including a “noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly.”

“When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.” B.F. Goodrich Co. v. Aircraft Braking Systems Corp., supra. The Examiner has pointed to nothing in the prior art which suggests the desirability of modifying any of **White, van Rooijen, Shults, Eifler, Yasuda ‘918, Yasuda ‘439, Yasuda ‘613, Tien, Raymond, Wohltjen, Stanbro** or **Pribat** as necessary to achieve Applicant’s claimed arrangement.

Furthermore, any use of **van Rooijen, Shults, Eifler, Yasuda ‘918, Yasuda ‘439, Yasuda ‘613, Tien, Raymond, Wohltjen, Stanbro** or **Pribat** as a reference under 35 U.S.C. § 103 would be improper because they are not analogous to Applicant’s invention. Again, In re Wood, supra., stated the rule for determining whether a prior art reference is or is not analogous art under 35 U.S.C. § 103:

Again, the Federal Circuit's common sense approach precludes broad interpretations of an invention's "field of endeavor" or what art is "reasonably pertinent." **van Rooijen, Shults, Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro and Pribat** relate to problems unrelated to Applicant's invention. Applicant's claimed invention relates to methods and apparatus for a "noise cancellation loop electrically distinct from the analyte reaction zone [of a test cell of a measurement loop on a substrate] and physically arranged to be exposed to substantially the same electromagnetic environment as the measurement loop and electrically connected to substantially cancel the effect of electromagnetically propagated field energy irradiating the biosensor cell assembly." **van Rooijen, Shults, Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro and Pribat** relate to problems unrelated to "cancellation . . . [of the] effect[s] of electromagnetically propagated field energy irradiating biosensor cell assembly [of a test cell of a measurement loop on a substrate]."

As a practical matter, an inventor in the field of methods and apparatus for addressing electromagnetically propagated field energy irradiating biosensor cell assemblies would not look to: **van Rooijen's** methods for ascertaining a relation between the capacitance of the working electrodes of electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis and the noise generated in such detectors; or **Shults's** charging of the electric double layers at the electrode-solution interface; or **Eifler's** method and sensing apparatus for obtaining an electrical signal which is a function of the oxygen content of the exhaust gas of an internal combustion engine; or **Yasuda '918's, Yasuda '439's, or Yasuda '613's** internal combustion engine exhaust gas component detection apparatus; or **Tien's** internal combustion engine exhaust gas component detector; **Raymond's** insulatively coated electrically conductive capacitor plates and leads, the insulative coating being chosen to be completely passive, non-reactive, and non-absorptive to the specific material sought to be detected and to other chemicals and materials present in the surrounding environment; or **Wohltjen's** method and apparatus to automatically compensate for temperature variation in a vapor detection system including two identical organic semiconductor film sensors, one isolated from vapor exposure by being completely passivated by a totally non-reactive layer in order to act as a reference for the other sensor which is used for vapor sampling; or **Stanbro's** ion exchange capacitive sensor and reference capacitive sensor with differential sensing; or **Pribat's** oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers for guidance. Thus, under Federal Circuit

precedent, **van Rooijen**, **Shults**, **Eifler**, **Yasuda ‘918**, **Yasuda ‘439**, **Yasuda ‘613**, **Tien**, **Raymond**, **Wohltjen**, **Stanbro** and **Pribat** are not within the same field of endeavor as Applicant’s claimed invention. *Clay, supra.*, *Wang Labs, supra.*

As the Federal Circuit highlighted in *Oetiker*, common sense limits the fields to which a person of ordinary skill would reasonably be expected to look for a solution. Just as the Federal Circuit in *Oetiker* criticized the Board’s “[apparent reasoning] that all hooking problems are analogous,” in the present case there is no basis for reasoning that all interference immunization problems are analogous. The problems related to “cancellation . . . [of the] effect[s] of electromagnetically propagated field energy irradiating biosensor cell assembly” are not reasonably pertinent to: the electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis of **van Rooijen**; the charging of electric double layers at electrode-solution interfaces of **Shults**; the methods and sensing apparatus for obtaining an electrical signal which is a function of the oxygen content of exhaust gas of an internal combustion engine of **Eifler**; the internal combustion engine exhaust gas component detection apparatus of **Yasuda ‘918**, **Yasuda ‘439**, and **Yasuda ‘613**; the internal combustion engine exhaust gas component detectors of **Tien**; the insulatively coated electrically conductive capacitor plates and leads of **Raymond**; the methods and apparatus to automatically compensate for temperature variation in a vapor detection system of **Wohltjen**; the ion exchange capacitive sensors and reference capacitive sensors with differential sensing of **Stanbro**; or, the oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers of **Pribat**.

Under the Federal Circuit’s “reality of the circumstances” or “common sense” rationale, it is unrealistic and not common sense to expect an inventor in the art of biosensor cell assemblies to look to: the electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis of **van Rooijen**; the charging of electric double layers at electrode-solution interfaces of **Shults**; the methods and sensing apparatus for obtaining an electrical signal which is a function of the oxygen content of exhaust gas of an internal combustion engine of **Eifler**; the internal combustion engine exhaust gas component detection apparatus of **Yasuda ‘918**, **Yasuda ‘439**, and **Yasuda ‘613**; the internal combustion engine exhaust gas component detectors of **Tien**; the insulatively coated electrically conductive capacitor plates and leads of **Raymond**; the methods and apparatus to automatically compensate for temperature variation in a vapor detection system of **Wohltjen**; the ion exchange capacitive sensors and reference capacitive sensors with

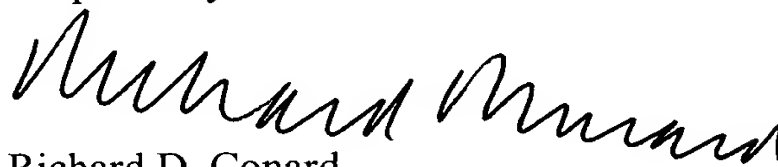
differential sensing of **Stanbro**; or, the oxygen sensor of the resistive type for closed loop control of the air-fuel mixtures supplied to internal combustion engines and forced air circulation-type boilers of **Pribat**.

Accordingly, Applicant submits that his claims 1-20 and 24-42, as previously presented, are in condition for favorable consideration, culminating in allowance. Such action is respectfully requested.

Applicant also encloses a supplemental disclosure statement pursuant to 37 C.F.R. § 1.56. No representation is intended that a complete search has been made of the prior art or that no better art references than listed below are available. A copy of each reference is provided for review by the Examiner. The filing of this disclosure statement shall not be construed to be an admission that the information cited in the disclosure statement is, or is considered to be, material to patentability as defined in §1.56(b).

Please charge any fees that might be due in connection with this response to our Deposit Account No. 10-0435, referencing our matter 5727-72828. An extra copy of this authorization is enclosed for that purpose.

Respectfully submitted



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